

New Report: Can biologic drugs tackle antibiotic resistance?

Date: 25.06.2008 - 14:18

Category: [Health & Medicine](#)

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The increase in resistance to and toxicity associated with some conventional antibiotics means that antibody-based products can represent a novel approach to the treatment and prevention of infections. Several companies have antibody-based agents in development for a range of infectious disease indications; however, their cost, complex manufacturing methods and mode of administration will restrict their use to certain therapeutic areas. A high unmet need as well as defined target groups are therefore key for commercial success for companies investing in this market, according to a new report by independent market analyst Datamonitor (www.reports-research.com/market-surveys/stakeholder-opini...).

Advances in technology as well as increase in resistance to conventional anti-infectives have led to a strong interest in the development of antibody based agents

Historically, serum-derived antibody therapy has been used to treat a wide range of infections, but safety concerns and the increased availability of anti-infective drugs led to their slow decline over the past five decades. However, advances in technology that improve manufacturing cost and tolerability have led to a renewed interest in the development of antibody-based agents for prophylaxis (prevention) and treatment of infectious diseases, says Datamonitor infectious diseases analyst Mansi Shah. "Fully human antibody reagents for example, avoid the toxicities associated with traditional human- or animal-derived serum therapy."

The emergence of new, as well as the re-emergence of old pathogens combined with an increasing prevalence of drug-resistant microorganisms have compromised the efficacy of existing therapeutic options. Moreover, the difficulties involved in preventing and treating infections in immuno-compromised patients have highlighted the need for adjunctive immunotherapy.

Despite the approval of the first monoclonal antibodies more than 20 years ago, only one antibody product has been successfully approved (Medimmune's Synagis for Respiratory Syncytial Virus prophylaxis) for an infectious disease indication. Now, however, several companies have such products in development for a range of infections. Earlier this year, Genentech announced its intention to enter this field. But, the advances in technology and the benefits of monoclonal antibodies are still largely offset by their cost, complex manufacturing methods and mode of administration, all of which will restrict their use to the treatment of certain infections, Ms Shah says. "Consequently, a high unmet need, as well as precisely defined target groups are key to demonstrate the favourable efficacy and cost-benefit profiles required to convince the regulatory and reimbursement gatekeepers.

"Antibody-based products that fulfil those criteria have a reasonable probability of commercial – as well as scientific success," she says.

Outside the hospital, the lack of either cure or preventative measures for many viral infections represents an opportunity for antiviral antibody development

Substantial progress has been made in the development of novel antiviral therapies over recent years, but the majority of new and existing products only inhibit and do not cure the infection. For many viral infections there remains no vaccine or other preventative measure available at all. At the same time, many antivirals are suffering from unfavourable side effect profiles and emerging resistances, Ms Shah says. "Antibody agents in development for viral infections such as HIV, and Hepatitis C (HCV) could potentially help overcome these issues.

"Medimmune's Synagis, a humanized antibody for the prophylaxis of RSV, represents the only success story so far with annual sales approaching \$1 billion. It was first approved in 1998 and in February its follow-on product motavizumab was

filed with the FDA,” she says.

While current HIV and HCV therapies may be associated with resistance and toxicity issues, the real unmet need lies in disease prevention and cure. Unfortunately, the majority of antibody agents in development are not addressing this issue. This factor, combined with their intravenous mode of administration will, in Datamonitor’s opinion, seriously restrict their use in these indications.

Antibody agents actually have a bigger role to play in the treatment and post exposure prophylaxis of infections such as Rabies, SARS and West Nile Virus, where there are no effective treatments or preventative measures available. Unfortunately, although infected individuals often require immediate protection, the markets for these indications are relatively small and possibly not commercially viable.

MRSA is the most popular nosocomial pathogen for antibody development, but the need for novel antifungal and Pseudomonas agents is greater

The need for alternative strategies to prevent and treat nosocomial infections has increased owing to the rise in number of medical procedures and number of immuno-compromised patients, alongside the growing resistance to conventional antibiotic therapy. Antibody-based products can offer patients fast and immediate protection and will benefit those unable to mount a sufficient immune response, like infants, the elderly and immuno-compromised patients. However, difficulties in identifying suitable targets on bacteria and defining high-risk patient populations are just some of the obstacles that manufacturers face in the development of these agents, Ms Shah says. “Moreover, given antibodies’ specificity and cost, their use will be restricted to either prior microbiologic diagnosis of the infection or a high prevalence rate of the respective pathogen, limiting their use to a small number of patients where the benefits are well defined.”

Since MRSA is the most common pathogen causing nosocomial infections, it has formed the most popular target for antibody development. However, despite concerns over resistance, there are still several antibiotics at hand that can treat multi-drug resistant strains of *S. aureus*. Because of this, antibodies are likely to have a limited role in the treatment of *S. aureus* infections in the medium-term, but may form effective prophylactic agents.

In the hospital environment, the greater need lies in the shortage of effective treatments for Pseudomonas and fungal infections. The hypervariability of Pseudomonas, however, has made the identification of targets for both antibody and vaccine development extremely difficult, Ms Shah says. “Antifungal antibodies are likely to be more successful commercially given the persistently high mortality rates associated with candidiasis and a slowly increasing prevalence of resistance to current antifungals.

“Severely immuno-compromised patients who are most at risk from such infections will benefit most from this immunotherapeutic approach that augments or replaces the host immune response. As such, anti-candida antibodies would form an attractive adjunct to conventional antifungal therapy,” she says.

The report: Stakeholder Opinions: Biologics in Infectious Diseases Well defined target populations are key to commercial success

(www.reports-research.com/market-surveys/stakeholder-opini...)

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